

5. 510(k) Summary

AUG 11 2011

Date prepared: July 7, 2011

K111282

This 510(k) is being submitted by Anthony Beran on behalf of Starboard Medical, LLC.

Contact:

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FDA Establishment Registration #: 3006845683

Contract Manufacturer:

Starboard Medical Jiangsu
Tel: 86-515-82306811
FDA Establishment Registration#: 3006845687

Trade Name:

The device trade name is Disposable Temperature probes/ sensors and Interconnect Instrument Cables.

Device common, usual, or classification names:

Skin temperature sensor
Tympanic temperature sensor
Interconnect Instrument Cables

Device Regulation:

21CFR880.2910, Clinical Electronic Thermometers

Classification:

Class II, product code FLL
Classification Panel: General Hospital

Predicate Device:

The following devices have been identified as predicate devices:

SMITHS LEVEL 1 Skin Temperature Sensor – K864195
SMITHS LEVEL 1 Tympanic Temperature Sensor – K873205

Description of device:

The Starboard Medical temperature sensors are intended for use in clinical situations where continuous monitoring of patient's body temperatures is required. The sensors are compatible with all monitoring instrumentation designed to accept YSI 400 series temperature sensors or

equivalent. The Interconnect Instrument cables are used to interconnect the disposable temperature probe / sensor with the patient monitor.

This 510(k) includes the following probes:

400-SK (Skin Temperature Sensor)
400-TY (Tympanic Temperature Sensor – Adult)
400-TYP (Tympanic Temperature Sensor – Pediatric)
C400MP-M (Interconnect Instrument Cable)
C400MP-MJ (Interconnect Instrument Cable)
C400P-M (Interconnect Instrument Cable)
C400P-MJ (Interconnect Instrument Cable)

The probes / sensors are single use, and they are sterile.

Intended Use:

Skin Temperature Sensor: The Starboard Medical Skin Temperature sensor is intended for continuous monitoring of skin temperature.

Tympanic Temperature Sensor: The Starboard Medical Tympanic Temperature sensor is intended for use in routine continuous monitoring of tympanic temperature as an indicator of core body temperature when this type of measurement is clinically indicated.

Technology Characteristics:

Both devices are substantially equivalent to the predicate devices based on material, technology, manufacturing processes, and performance.

Performance Data:

Both devices have been subjected to materials bio-compatibility testing, accuracy testing, and electrical testing and comparison.

Conclusion:

We believe the differences between the Starboard Medical devices and the predicate devices are minor, and conclude that the subject devices are as safe and effective as the predicate devices, therefore substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Anthony Beran
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AUG 11 2011

Re: K111282
Trade/Device Name: Disposable Temperature Probes/ Sensors and Interconnect
Instruments
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 8, 2011
Received: July 15, 2011

Dear Mr. Beran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

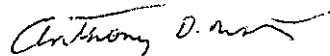
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): Unknown.

K111282

Device Name(s):

Skin Temperature Sensor, Catalog Numbers 400-ST5

Tympanic Temperature Sensor, Catalog Numbers 400-TY, 400-TYP

Interconnect Instrument Cables Catalog Numbers C400MP-M, C400MP-MJ, C400P-M, C400P-MJ

Indications for Use:

Skin Temperature Sensor (400-ST5)

The Starboard Medical Skin temperature sensor is indicated for continuous patient temperature monitoring when the skin placement site is clinically recommended. The sensor is designed for placement on the surface of the skin.

Tympanic Temperature Sensor (400-TY, 400-TYP)

The Starboard Medical Tympanic Temperature sensor is indicated for continuous monitoring of patient temperature when the ear canal placement site is clinically recommended. The probe is designed for insertion into the ear canal in the proximity of the Tympanic membrane.

Interconnect Instrument Cables (C400MP-M, C400MP-MJ, C400P-M, and C400M-MJ)

The instrument cables are indicated for interconnecting the disposable temperature sensor or probe with the monitoring instrument.

Prescription Use: XXXX
(Part 21CFR801 Subpart D)

and/or

Over-the-Counter Use: _____
(Part 21CFR801 Subpart C)

R. C. Chapp 8/10/4
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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